

REMARKS

This Amendment is submitted in reply to the Final Office Action mailed on December 9, 2009. The Commissioner is hereby authorized to charge for any fees which may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036-00697 on the account statement.

Claims 1 and 3-12 are pending in the application. Claim 2 was previously canceled without prejudice or disclaimer. In the Office Action, Claims 1 and 3-12 are rejected under 35 U.S.C. §103(a). In response, Applicants have amended Claims 1, 3 and 5-12 and have newly added Claim 13. The amendments and newly added claims do not add new matter and are supported in the specification at, for example, page 6, line 4-page 7, line 25. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the rejections be reconsidered and withdrawn.

In the Office Action, Claims 1 and 3-12 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2003/0181401 to Takada et al. ("Takada") in view of Eur. J. Nutr., 2002, 41 (Suppl 1), p. I/17-I/25 to Schumann ("Schumann") and in view of CRC Handbook of Dietary Fiber in Human Nutrition, 2001 3rd Ed. P. 373-400 to Spiller ("Spiller"). In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the cited references are deficient with respect to the present claims.

Currently amended independent Claims 1 and 5 recite, in part, methods for treating and/or improving insulin resistance comprising administering to a patient a composition comprising lactulose, a protein source in an amount from about 21 to about 40% by weight of the composition, a lipid source in an amount from about 5% to about 40% of the total energy of the composition, and a carbohydrate source in an amount that is less than 10% by weight of the composition. The amendment does not add new matter and is supported in the specification at, for example, page 7, lines 5-25. Surprisingly, the present inventors have found that acetogenic fibers have significant effects in improving insulin sensitivity, and in particular, in reestablishing normal insulin sensitivity and thus a normal systemic metabolism. See, specification, page 4, lines 15-17. Without wishing to be bound to any theory it is presently assumed that an increased amount of acetate in blood and tissues – resulting from an administration of a composition according to the present invention results in reduced lipolysis, *i.e.*, a reduced liberation of

glycerol and fatty acids from tissues into the blood. This could result in a reduction in the amount of free fatty acids inactivating insulin receptors, which, in turn, could result in an improvement in insulin sensitivity even to the levels present in healthy persons. See, specification, page 5, lines 17-22. In contrast, Applicants submit that the cited references are deficient with respect to the present claims.

For example, *Takada*, *Schumann* and *Spiller* all fail to disclose or suggest methods for treating and/or improving insulin resistance comprising administering to a patient a composition comprising lactulose, a protein source in an amount from about 21 to about 40% by weight of the composition, a lipid source in an amount from about 5% to about 40% of the total energy of the composition, and a carbohydrate source in an amount that is less than 10% by weight of the composition as required, in part, by the present claims. Instead, *Takada* teaches compositions containing di- or higher saccharides for promoting insulin secretion. While *Takada* discloses the composition present in a food, *Takada* fails to mention the presently claimed protein, lipid and carbohydrate amounts. See, *Takada*, Abstract. *Schumann* teaches the pharmacodynamics and prebiotic action of lactulose. See, *Schumann*, Abstract. *Spiller* teaches the effects of dietary fiber in the human diet, and specifically, the effects of dietary fiber with respect to diabetes. See, *Spiller*, pages 373-391.

However, at no place in any of the above mentioned references, does the disclosure mention methods for treating and/or improving insulin resistance comprising administering to a patient a composition comprising lactulose, a protein source in an amount from about 21 to about 40% by weight of the composition, a lipid source in an amount from about 5% to about 40% of the total energy of the composition, and a carbohydrate source in an amount that is less than 10% by weight of the composition. Therefore, *Takada*, *Schumann* and *Spiller* fail to disclose or suggest each and every element of the present claims.

Further, Applicants have newly added Claim 13, which recites, in part, methods for treating and/or improving insulin resistance by administering to a patient in need of same an effective amount of a composition comprising lactulose, wherein the composition is administered between 3 and 7 hours before a meal. Newly added Claim 13 does not add new matter and is supported in the specification at, for example, page 6, lines 4-11. Applicants respectfully submit that the cited references are also deficient with respect to newly added Claim 13.

For example, *Takada*, *Schumann* and *Spiller* all fail to disclose or suggest administration of lactulose about 3 to 7 hours before a meal. Instead, *Takada* is directed to a disaccharide that may be administered in a composition as a meal. At no place in the disclosure does *Takada* disclose or suggest that the disaccharide be administered about 3 to 7 hours before a meal. Additionally, neither *Schumann* nor *Spiller* disclose administering lactulose at any time with respect to a meal, let alone about 3 to 7 hours before a meal. For at least these reasons, Applicants respectfully submit that the obviousness rejection of Claims 1 and 3-12 is improper and that the cited references fail to disclose or suggest each and every element of the presently claimed subject matter.

Accordingly, Applicants respectfully request that the obviousness rejection of Claims 1 and 3-12 be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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